

**CORPORATE INTEGRITY AGREEMENT**  
**BETWEEN THE**  
**OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN**  
**SERVICES**  
**AND**  
**ST. JOSEPH'S MEDICAL CENTER**

**I. PREAMBLE**

St. Joseph's Medical Center ("SJMC") hereby agrees to enter into this Corporate Integrity Agreement ("Agreement") with the Office of Inspector General of the United States Department of Health and Human Services ("OIG") to provide for the establishment of a Corporate Integrity Program ("Program") to ensure compliance with the billing and reimbursement requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) by SJMC, its employees and all third parties with whom SJMC may choose to engage to act as billing or coding consultants for SJMC.

The Program shall be maintained with the aim to ensure that SJMC and each of its directors, officers, employees, contractors and agents maintain the business integrity required of a participant in Federal health care programs, and that SJMC's billings for medical care and related reimbursable expenses are in effective compliance with all statutes, regulations and guidelines applicable to such programs and with the terms of this Agreement as set forth below. SJMC is entering into a settlement agreement with the United States and this Agreement is incorporated into that Settlement Agreement by reference.

Prior to the execution of this Agreement, SJMC voluntarily adopted and is in the process of implementing a Compliance Plan dated October 1998 ("Compliance Plan"), which provides for corporate integrity policies and procedures and which, as represented by SJMC in this Agreement, is aimed at ensuring that its participation in the Federal health care programs (which includes any requests for payments from Federal health care programs) is in conformity with the statutes, regulations, and other directives applicable to the Federal health care programs. Therefore, pursuant to this Agreement, SJMC hereby agrees to maintain in full operation the Compliance Plan for the term of this Agreement. The Compliance Plan may be modified by SJMC as appropriate, but, at a

minimum, shall always comply with integrity obligations enumerated in this Agreement. SJMC shall notify OIG of any substantive changes to Sections 9, 13, 16, 24, 26 and 27 of the Compliance Plan within thirty days of making such changes.

## **II. TERM OF THE AGREEMENT**

Except as otherwise provided, the period of compliance obligations assumed by SJMC under this Agreement shall be three (3) years from the effective date of this Agreement.

## **III. CORPORATE INTEGRITY OBLIGATIONS**

Pursuant to this Agreement, and for the duration of this Agreement, SJMC will make the following integrity obligations permanent features of its Compliance Plan, which shall be established in accordance with the provisions below:

### **A. CORPORATE COMPLIANCE OFFICER AND COMMITTEE**

SJMC has represented to OIG that, pursuant to its Compliance Plan, it has created a Compliance Officer position and has appointed an individual to serve in that capacity. Accordingly, SJMC shall formally maintain the appointment of an individual to serve as the Compliance Officer. At a minimum, the Compliance Officer must continuously be charged with the responsibility for the day-to-day compliance activities in furtherance of the integrity obligations assumed herein, as well as for any reporting obligations established under this Agreement. The Compliance Officer must report directly to the President of SJMC and to the Chairperson of SJMC's Board of Trustees and shall have unrestricted access to the Board of Trustees for SJMC. The Compliance Officer shall be a member of management and shall make regular (at least quarterly) reports regarding compliance matters directly to SJMC's President and/or to the Board of Trustees of SJMC. When the identity of the Compliance Officer changes, SJMC shall notify, in writing, the OIG within fifteen (15) days of such change. All other matters affecting the Compliance Officer's responsibilities with respect to this Agreement and the Compliance Plan shall be reported in accordance with Section VI below.

SJMC has represented to OIG that, pursuant to its Compliance Plan, it has created a Compliance Committee. Accordingly, SJMC shall formally maintain a

Compliance Committee, which shall be responsible for, at a minimum, compliance with the integrity obligations in this Agreement. SJMC shall ensure that the Compliance Committee is continuously composed of representatives of multiple disciplines and segments of SJMC's operations. At a minimum, the Compliance Committee shall include the Compliance Officer and any other appropriate officers as necessary to meet the requirements of this Agreement (e.g., senior executives of each major department, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities.

**B. WRITTEN STANDARDS**

1. *Code of Conduct.* SJMC has represented to OIG that it has adopted its Code of Conduct and is implementing its Compliance Plan. Accordingly, SJMC shall formally maintain the written Code of Conduct and implement its Compliance Plan within ninety (90) days of the effective date of this Agreement. SJMC is implementing and shall maintain a Compliance Plan which shall at a minimum set forth:

- a. SJMC's commitment to full compliance with all statutes, regulations, and guidelines applicable to Federal health care programs, including its commitment to prepare and submit accurate billings consistent with Federal health care program regulations and procedures or instructions otherwise communicated by the Health Care Financing Administration ("HCFA") (or other appropriate regulatory agencies) and/or its agents;
- b. SJMC's requirement that all of its employees and billing or coding consultants shall be expected to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with SJMC's own policies and procedures (including the requirements of this Agreement);
- c. the requirement that all of SJMC's employees and billing or coding consultants shall be expected to report suspected violations of any statute, regulation, or guideline applicable to Federal health care programs or of SJMC's own policies and procedures;

- d. the possible consequences to both SJMC and to any employee or agents of failure to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with SJMC's own policies and procedures or of failure to report such non-compliance; and
- e. the right of all employees, contractors or agents to use the confidential disclosure program, as well as SJMC's commitment to confidentiality and non-retaliation with respect to disclosures.

SJMC shall formally maintain its written Code of Conduct that includes disciplinary guidelines and methods for employees to make disclosures or otherwise report on compliance issues to SJMC management through the Confidential Disclosure Program required by section III.E. SJMC shall review the Code of Conduct at least annually and revise the Code of Conduct as necessary.

Compliance staff or supervisors should be available to explain applicable provisions of the Code of Conduct. SJMC shall distribute to its employees any substantive changes to its Code of Conduct applicable to such employees. Billing or coding consultants for SJMC will be informed of any material change to its Code of Conduct applicable to such consultant.

Within ninety (90) days of the effective date of the Agreement, a summary of SJMC's Compliance Plan shall have been distributed by SJMC to all employees and selected third parties with whom SJMC may engage to act as billing or coding consultants for SJMC. Each employee shall certify, in writing, that he or she has read the summary of SJMC's Compliance Plan and understands and will abide by SJMC's Compliance Plan. This certification will also be required whenever a substantive change to the Compliance Plan is enacted. New employees shall receive a summary of SJMC's Compliance Plan and training regarding the Compliance Plan - within sixty (60) days after commencement of their employment. When the training has been completed these individuals shall certify, in writing, that he or she has read the summary of SJMC's Compliance Plan and understands and will abide by SJMC's Compliance Plan.

2. *Policies and Procedures.* Within ninety (90) days of the effective date of this Agreement, SJMC shall develop and initiate implementation of written Policies and Procedures regarding the operation of SJMC's compliance program. The Policies and Procedures, the Code of Conduct or Billing Department Policies or Procedures shall specifically address the billing of ancillary pharmacy charges. In addition, the Policies and Procedures, the Compliance Plan, or Human Resources Policies and Procedures shall include disciplinary guidelines and methods for employees to make disclosures or otherwise report on compliance issues to SJMC's management through the Confidential Disclosure Program required by section III.E. SJMC shall assess and update as necessary the Policies and Procedures at least annually. A summary or copy of the Policies and Procedures will be provided to OIG in the Implementation Report. The Policies and Procedures will be available to OIG upon request.

Within ninety (90) days of the effective date of the Agreement, those portions of the Policies and Procedures shall be made available to all applicable employees, contractors or agents. Compliance staff or supervisors should be available to explain any and all policies and procedures.

C. **TRAINING AND EDUCATION**

1. *General Training.* Within ninety (90) days after the effective date of this Agreement, each employee of SJMC shall have completed at least one (1) hour of general training. This general training shall: (1) cover SJMC's Compliance Plan; (2) cover SJMC's Code of Conduct as appropriate for the type of employee; (3) reinforce the need for strict compliance with the applicable statutes, regulations, program guidelines, and SJMC's Code of Conduct; and (4) advise employees how potential violations of these authorities should be handled and that any failure to comply may result in disciplinary action, up to termination of employment. New employees shall receive the general training described above within sixty (60) days of the beginning of their employment or within ninety (90) days after the effective date of this Agreement, whichever is later.

2. *Billing Training.* In addition to the general training described above, each employee who is responsible for the preparation or submission of

claims for reimbursement to Medicare, Medicaid, or any other Federal health care programs shall receive at least eight (8) hours of training within ninety (90) days after the effective date of this agreement in: (i) the submission of accurate bills for services rendered to Medicare and/or Medicaid patients; (ii) the importance of each individual involved in the billing process to ensure that such billings are accurate; (iii) applicable reimbursement rules and statutes; (iv) the legal sanctions for improper billings; (v) examples of proper and improper billing practices; and (vi) for those individuals responsible for preparing claims for ancillary pharmacy charges, a review of proper billing procedures for ancillary pharmacy charges. Persons providing the training may be employees or agents of SJMC and must have the requisite expertise and qualifications to conduct the required training.

Affected new employees shall receive this training within sixty (60) days of the beginning of their employment. If a new employee is responsible for the assignment of procedure codes prior to completing this coding training, a SJMC employee who has completed the coding training shall review all of the untrained person's work regarding the assignment of procedure codes until the new employee has completed their training. Every employee shall receive such specific training each year.

Each affected employee shall certify, in writing, that he or she has attended the required training. The certification shall specify the type of training received and the date received. The Compliance Officer shall retain the certifications, along with specific course materials during the term of this Agreement. These shall be made available to OIG upon request. SJMC shall certify that such training has been provided in its Implementation and Annual Reports to OIG, in accordance with section V.

#### **D. REVIEW PROCEDURES**

Within ninety (90) days of the effective date of this Agreement, SJMC shall establish its internal review group or retain an entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization"), to perform review procedures to assist SJMC in assessing the adequacy of its billing and compliance practices pursuant to this Agreement. This shall be an annual requirement and shall cover a twelve (12) month period. The internal review group or Independent Review Organization must have expertise in the billing, coding,

reporting and other requirements of the Federal health care programs from which SJMC seeks reimbursement. Prior to each review and audit, SJMC (or its designee) shall prepare and submit for review to OIG the work plan describing the protocols it proposes to follow in conducting the review and audit. The internal review group must be established and/or the Independent Review Organization must be retained to conduct the audit of the first year within ninety (90) days of the effective date of this Agreement.

Two separate engagements will be required pursuant to this Agreement. One will be an analysis of SJMC's billing to the Federal health care programs to assist SJMC and OIG in determining compliance with all applicable statutes, regulations, and directives/guidance ("billing engagement"). The second engagement will determine whether SJMC is in compliance with this Agreement ("compliance engagement").

1. *Billing Engagement.* The billing engagement shall consist of a review of a statistically valid sample of claims that can be projected to the population of claims for the relevant period. The sample size shall be determined through the use of a probe sample. At a minimum, the full sample must be within a ninety (90) percent confidence level and a precision of twenty-five (25) percent. The probe sample must contain at least thirty (30) sample units and cannot be used as part of the full sample. Both the probe sample and the sample must be selected through random numbers. SJMC shall use OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS," which is available through the Internet at "<http://www.hhs.gov/progorg/oas/ratstat.html>".

Each annual billing engagement analysis shall include the following components in its methodology:

- a. **Billing Engagement Objective:** A statement stating clearly the objective intended to be achieved by the billing engagement and the procedure or combination of procedures that will be applied to achieve the objective.
- b. **Billing Engagement Population:** Identify the Federal health care program beneficiary population, which is the group about which information is needed. Explain the methodology used to develop the

population and provide the basis for this determination.

c. **Sources of Data:** Provide a full description of the source of the information upon which the billing engagement conclusions will be based, including a statement that they relied upon applicable legal or other standards, documents relied upon, payment data, and/or any contractual obligations.

d. **Sampling Unit:** Define the sampling unit, which is any of the designated elements that comprise the population of interest.

e. **Sampling Frame:** Identify the sampling frame, which is the totality of the sampling units from which the sample will be selected.

The billing engagement shall provide:

a. findings regarding SJMC's billing and coding operation (including, but not limited to, the operation of the billing system, strengths and weaknesses of this system, internal controls, effectiveness of the system);

b. findings regarding whether SJMC is submitting accurate claims for services billed to the Federal health care programs.

c. findings regarding SJMC's procedures to correct inaccurate billings to the Federal health care programs;

d. findings regarding SJMC's billing of ancillary pharmacy charges; and

e. findings regarding the steps SJMC is taking to bring its operations into compliance or to correct problems identified by the audit.

Upon completion of an internal audit by the internal review group, SJMC shall contract with an Independent Review Organization to verify the methodology applied in the internal audit and the findings and conclusions of the internal reviewers. If OIG is not satisfied with the objectivity and effectiveness of the internal audits performed by SJMC's internal review



group, SJMC agrees that it will contract with an Independent Review Organization, at its own expense to review and audit on an annual basis the billing policies, procedures and practices of SJMC.

*2. Compliance Engagement.* An Independent Review Organization shall also conduct a compliance engagement, that shall provide findings regarding whether SJMC's Program, policies, procedures, and operations comply with the terms of this Agreement. This engagement shall include section by section findings regarding the requirements of this Agreement.

A complete copy of the billing and compliance engagements performed by the Independent Review Organization(s) shall be included in each of SJMC's Annual Reports to OIG.

*3. Disclosure of Overpayments and Material Deficiencies.* If, as a result of these engagements, SJMC or the Independent Review Organization identifies any billing, coding or other policies, procedures and/or practices that result in an overpayment from the Federal health care programs, SJMC shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within thirty (30) days of SJMC discovering the deficiency or overpayment and take remedial steps within sixty (60) days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the deficiency from recurring. The notice to the payor shall include:

- a. a statement that the refund is being made pursuant to this Agreement;
- b. a description of the complete circumstances surrounding the overpayment;
- c. the methodology by which the overpayment was determined;
- d. the amount of the overpayment;
- e. any claim-specific information used to determine the overpayment (e.g., beneficiary health insurance number, claim number, service date, and payment date);
- f. the cost reporting period; and
- g. the provider identification number under which the repayment is being made.

If SJMC determines an overpayment under Federal health care programs

represents a material deficiency, contemporaneous with SJMC's notification to the payor as provided above, SJMC shall also notify OIG of:

- a. a complete description of the material deficiency;
- b. amount of overpayment due to the material deficiency;
- c. SJMC's action(s) to correct and prevent such material deficiency from recurring;
- d. the payor's name, address, and contact person where the overpayment was sent;
- e. the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid.

For purposes of this Agreement, an "overpayment" shall mean the amount of money the provider has received from a Federal health care program in excess of the amount due and payable under the Federal health care programs' statutes, regulations or program directives, including carrier and intermediary instructions.

For the purposes of this Agreement, a "material deficiency" shall mean anything that involves: (i) a substantial overpayment or improper payment relating to the Medicare and/or Medicaid programs; (ii) conduct or policies that clearly violate the Medicare and/or Medicaid statutes, or regulations or directives issued by HCFA and/or its agents; or (iii) serious quality of care implications for federal health care beneficiaries or recipients. A material deficiency may be the result of an isolated event or a series of occurrences.

4. *Verification/Validation.* In the event that the OIG determines that it is necessary to conduct an independent review to determine whether or the extent to which SJMC is complying with its obligations under this Agreement, SJMC agrees to pay for the reasonable cost of any such review or engagement by the OIG or any of its designated agents. OIG will notify SJMC thirty (30) days before they engage an entity to perform such a review.

#### **E. CONFIDENTIAL DISCLOSURE PROGRAM**

SJMC has represented to OIG that, pursuant to its Compliance Plan, it has created a Confidential Disclosure Program ("CDP"). SJMC shall formally maintain its CDP

for the term of this Agreement. At a minimum, SJMC's CDP shall enable employees, agents and contractors, if applicable, to disclose to the Compliance Committee and/or Compliance Officer, or some other person who is not in the reporting individual's chain of command, any identified issues or questions associated with the policies, practices or procedures with respect to Medicare, Medicaid, or any other Federal health care program, alleged by the individual to be inappropriate.

SJMC's CDP shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. The SJMC Compliance Officer, upon receipt of a complaint shall gather information in such a way as to elicit all relevant information from individuals reporting alleged misconduct. The Compliance Officer and/or Compliance Committee shall make a preliminary good faith inquiry into the allegations set forth in every disclosure to ensure that it has obtained all of the information necessary to determine whether it should conduct further review. Moreover, SJMC shall, as part of its CDP, require the investigation of any disclosure that is sufficiently specific so that it: (1) permits a determination of the appropriateness of the practice alleged to be involved; and (2) reasonably permits corrective action to be taken and ensures that proper follow-up is conducted.

The Compliance Officer also shall maintain a confidential disclosure log, which shall include a record of each allegation received, status of the investigation of the allegation, and any corrective action taken in response to the investigation.

SJMC shall include in its Annual Report to OIG a summary of communications received from the Confidential Disclosure Program and the results of any investigations performed as a result of these disclosures. OIG will endeavor to afford the information furnished by SJMC regarding the disclosure program the utmost confidentiality, subject to federal laws, such as the Freedom of Information Act, if applicable. To the extent feasible, and at OIG's option, OIG may also review the documentation on SJMC's premises. In turn, SJMC agrees to maintain such reports in a manner agreeable to OIG so that they will be readily available to OIG for a minimum of four (4) years or one (1) year longer than the duration of this Agreement.

## **F. INELIGIBLE PERSONS**

1. *Definition.* For purposes of this Agreement, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

2. *Screening Requirements.* SJMC shall not hire or engage as contractors or grant staff privilege to any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, SJMC shall screen all prospective employees and prospective contractors prior to engaging their services and screen physicians prior to granting staff privileges by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.arnet.gov/epls>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.dhhs.gov/progorg/oig>) (these lists and reports will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement.* Within ninety (90) days of the effective date of this Agreement, SJMC will review its list of current employees and contractors and physicians with staff privileges against the Exclusion Lists. Thereafter, SJMC will review the lists once every six (6) months. If SJMC has notice that an employee, agent, or physician has become an Ineligible Person, SJMC will remove such person from responsibility for, or involvement with, SJMC business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If SJMC has notice or upon discovery that an employee, contractor or physician with staff privileges is

charged with a criminal offense related to any Federal health care program, or is suspended or proposed for exclusion during his or her employment or contract with SJMC, within ten (10) business days of receiving such notice or discovering that such a charge exists, SJMC will remove such individual from responsibility for, or involvement with, SJMC business operations related to the Federal health care programs until the resolution of such criminal action, suspension, or proposed exclusion. With respect to physicians with staff privileges, SJMC shall effectuate this provision as soon as possible, but in no event later than March 13, 2000.

In the event that any requirement in this section III.F. cannot be carried out because of a conflict with a provision or term of a collective bargaining agreement, SJMC agrees to notify OIG within seven (7) days of its identification of such conflict. The parties shall endeavor to resolve any such conflict.

#### **IV. OIG INSPECTION, AUDIT AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, contract or pursuant to this Agreement, OIG or its duly authorized representative(s) or agents may examine SJMC's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (i) SJMC's compliance with the terms of this Agreement; and (ii) SJMC's compliance with the requirements of the Medicare, Medicaid and other Federal health care programs. The documentation described above shall be made available by SJMC at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of SJMC's employees who consent to be interviewed at the employee's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee and OIG. SJMC agrees to assist OIG in contacting and arranging interviews at reasonable times and with reasonable notice with such employees upon OIG's request. SJMC employees may elect to be interviewed with or without a representative of SJMC and with or without an attorney present.

#### **V. IMPLEMENTATION AND ANNUAL REPORTS**

Within one-hundred and twenty (120) days after the effective date of this Agreement, SJMC shall submit a written report to the OIG summarizing the status of implementation of the requirements of this Agreement. This implementation report shall

include:

- (1) the name, address, phone number and title of the Compliance Officer and members of the Compliance Committee, as required in section III.A.;
- (2) any substantive revisions or amendments made to SJMC's Compliance Plan or Code of Conduct subsequent to the effective date of this Agreement; a certification from the Compliance Officer that the written Code of Conduct required by section III.B. has been developed, is being implemented, and that each affected employee who is subject to the training requirement has signed the certification attesting that they have received, read, understood and will abide by the applicable portions of SJMC's Code of Conduct;
- (3) a description of the training programs implemented to date pursuant to section III.C. and a summary of the activities undertaken in furtherance of the training programs, including schedules and format of the training sessions;
- (4) the identity of the internal review group and/or Independent Review Organization(s);
- (5) a summary of personnel actions taken pursuant to section III.F.;
- (6) any other facilities acquired by, established by, or newly managed by SJMC since the execution of this Agreement; and
- (7) a copy of the Policies and Procedures developed in accordance with section II.B.2 of this Agreement.

Thereafter, SJMC shall submit to the OIG an Annual Report, with respect to the status and findings of SJMC compliance activities.

The Annual Reports shall include:

- (1) any change in the identity or position description of the Compliance Officer, or in the make-up of the compliance committee described in section III.A.;
- (2) pursuant to section III.B., a certification from SJMC's Compliance Officer that copies of SJMC's employees' and applicable third parties' certifications are on file

and will be maintained for OIG inspection;

(3) the Compliance Officer's certification that all affected employees have attended training sessions as well as a summary of when the training was performed and the proposed schedule for the next year, pursuant to section III.C. The training materials will be available to the OIG upon request;

(4) pursuant to section III.D., a complete copy of the billing audit and compliance engagements performed by the internal review group and/or the Independent Review Organization(s) and any future corrective actions SJMC plans to initiate and when;

(5) pursuant to section III.D., a summary of problems identified in the billing audit; status of corrective actions taken to address those problems; for each identified overpayment include the following information: amount of individual overpayments identified and repaid, the provider identification of the facility which submitted the overpayment, the corresponding payor's name to which the overpayment was sent, the date of the check and check number (or electronic transaction number) on which overpayment was repaid;

(6) a report of the aggregate overpayments that have been returned to the Medicare, Medicaid, and other Federal health care programs that were discovered as direct or indirect result of the corporate integrity provisions in this Agreement.

Overpayment amounts should be broken down into the following categories: Medicare, Medicaid (report each applicable state separately) and other Federal health care programs. For any overpayments not identified through the billing audit pursuant to section III.D., include a description of how each overpayment was calculated and the reason for the overpayment;

(7) A summary of communications received from the confidential disclosure program pursuant to section III.E.;

(8) a complete description of any personnel action (other than hiring) taken by SJMC as a result of the obligations in section III.F.;

(9) a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity where SJMC is a target of the investigation or legal proceeding involving a charge that SJMC has committed a crime or has

engaged in fraudulent activities. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such an inquiry, legal proceeding or requests for information;

(10) a listing of all of SJMC's locations (street, city, state, zip), the corresponding name each location is doing business as, each location's Federal health care program provider identification number(s) and the payor (specific contractor) who issued each provider identification number; and

(11) a certification by the Compliance Officer verifying that: (i) SJMC is in compliance with all of the requirements of this Agreement, to the best of his or her knowledge, and (ii) the Compliance Officer has reviewed the Annual Report and has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

The first Annual Report shall be received by the OIG no later than one (1) year and thirty (30) days after the effective date of this Agreement. Subsequent Annual Reports are due within thirty (30) days after the end of each annual period.

#### **VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in a writing agreed to by SJMC and the OIG subsequent to the execution of this Agreement, all notifications and reports required under the terms of this Agreement shall be submitted to the entities listed below:

OIG: Civil Recoveries Branch - Compliance Unit  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
330 Independence Avenue, SW  
Cohen Building, Room 5527  
Washington, DC 20201  
Phone 202.619.2078  
Fax 202.205.0604

St. Joseph's Medical Center:

Sr. Mary Linehan, President



Mary O'Mara, Compliance Officer  
St. Joseph's Medical Center  
127 South Broadway  
Yonkers, New York  
Phone 914.378.7506(President); 914.378.7514 (Comp. Officer)  
Fax 914.965.4838  
Medicare Provider Number:

**VII. DOCUMENT AND RECORD RETENTION**

SJMC shall maintain for inspection documents and records relating to reimbursement from the Federal health care programs or with compliance with this Agreement one year longer than the duration of this Agreement or until otherwise required by law to retain such records, whichever is later.

**VIII. BREACH AND DEFAULT PROVISIONS**

SJMC's compliance with the terms and conditions in this Agreement shall constitute an element of SJMC's present responsibility with regard to participation in federal programs. Best efforts to achieve full and timely compliance by SJMC shall be expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by SJMC. As stated below in section IX of this Agreement, any and all modifications to this Agreement (including changes to dates on which an obligation is due to be met) shall be requested in writing and agreed to by OIG in writing prior to the date on which the modification is expected to take effect.

**A. STIPULATED PENALTIES FOR FAILURE TO COMPLY WITH CERTAIN OBLIGATIONS**

As a contractual remedy, SJMC and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement may lead to the imposition of the following monetary penalties (hereinafter referred to as "stipulated penalties") in accordance with the following provisions:

- (1) A Stipulated Penalty of \$2,500 (which shall begin to accrue on the first business day after the date the obligation became due) for each day SJMC fails to have in place any of the following during the entire period beginning one-hundred and twenty (120) days after the effective date of this Agreement and concluding at

the end of the corporate integrity period required by this Agreement:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. written Code of Conduct;
- d. an education and training program;
- e. a mechanism for obtaining compliance audits and reporting material deficiencies; and
- f. a Confidential Disclosure Program.

(2) A Stipulated Penalty of \$2,500 (which shall begin to accrue on the first business day after the date the obligation became due) for each day SJMC fails meet any of the deadlines to provide the Implementation Report or the Annual Reports.

(3) A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day SJMC:

- a. hires or enters into a contract with an Ineligible Person after that person has been listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Medicare, Medicaid or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)) (this Stipulated Penalty shall not be demanded for any time period during which SJMC can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person);
- b. employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, SJMC's business operations related to the Federal health care programs or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (this Stipulated Penalty shall not be demanded for any time period during which SJMC can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person); or

c. employs or contracts with a person who: (i) has been charged with a criminal offense related to any Federal health care program, or (ii) is suspended or proposed for exclusion, and that person has responsibility for, or involvement with, SJMC's business operations related to the Federal health care programs (this Stipulated Penalty shall not be demanded for any time period before ten (10) days after SJMC received notice of the relevant matter or after the resolution of the matter).

(4) A stipulated penalty of \$1,500 (which shall begin to accrue on the date that SJMC fails to grant reasonable access) for each business day SJMC fails to grant reasonable access to the information or documentation necessary to exercise OIG's inspection, audit and review rights set forth in section IV of this Agreement.

(5) A Stipulated Penalty of \$1,000 (which shall begin to accrue ten (10) days after SJMC's receipt of notice of the failure to comply) for each day SJMC fails to comply fully and adequately with any other obligation of this Agreement other than those specifically mentioned in paragraphs (1) through (4) of this section VIII.A. In its notice to SJMC, OIG shall state the specific grounds for its determination that SJMC has failed to comply fully and adequately with the obligation(s) of the Agreement at issue.

**B. PAYMENT OF STIPULATED PENALTIES**

Upon finding that SJMC has failed to comply with any of the above-enumerated obligations, OIG shall notify SJMC in writing, and deliver personally or by certified mail notice of: (i) SJMC failure to comply; and (ii) OIG's exercise of its contractual right to demand payment of the stipulated penalties payable under this Agreement (this notification of the OIG's notice of noncompliance is hereinafter referred to as the "Demand Letter").

Within ten (10) business days of receipt of the Demand Letter, SJMC shall respond by either: (i) curing the breach to the OIG's satisfaction, paying the applicable stipulated penalties and notifying OIG of its corrective actions; or (ii) sending in writing to the OIG a request for a hearing before an HHS administrative law judge to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth in section VIII.D of this Agreement. Failure to respond to the Demand Letter within the ten (10) business day period shall be considered a material breach of this Agreement and shall be grounds for exclusion under section

VIII.C below.

If SJMC submits a timely written request to HHS-OIG for an extension of the relevant time period to perform any act or file any notification or report under this Agreement, but such an extension is denied, HHS-OIG agrees that Stipulated Penalties shall not begin to accrue until two (2) business days following SJMC receipt of HHS-OIG's written denial of such an extension. A "timely written request" is defined as a request in writing received by HHS-OIG at least five (5) business days prior to the date by which any act is due to be performed or notification or report is due to be filed.

Payment of the stipulated penalties shall be made by certified or cashier's check, payable to "Secretary of the Department of Health and Human Services," and submitted to OCIG at the address set forth in section VI of this Agreement.

Except as otherwise noted above, these provisions for payment of stipulated penalties shall not affect or otherwise set a standard for the OIG's determination that SJMC has materially breached this Agreement, which decision shall be made at the OIG's discretion and governed by the provisions in section VIII.C of this Agreement, below.

**C. REMEDIES FOR MATERIAL BREACH OF THIS AGREEMENT**

If SJMC engages in conduct that OIG considers to be a material breach, defined below, of this Agreement, OIG may seek exclusion of SJMC from participation in the Medicare, Medicaid and any other Federal health care programs. Upon making its determination, OIG shall notify SJMC of the alleged material breach by certified mail and of its intent to exclude as a result thereof (this notice shall be referred to hereinafter as the "Notice of Material Breach and Intent to Exclude Letter"). SJMC shall have thirty-five (35) days from the date of the letter to:

- (1) demonstrate to the OIG's satisfaction that SJMC is in substantial compliance with the Agreement; or
- (2) cure the alleged material breach; or
- (3) demonstrate to the OIG's satisfaction that the alleged material breach cannot be cured within the thirty-five (35) day period, but that SJMC has begun to

take action to cure the material breach and that SJMC will pursue such an action with due diligence. SJMC shall, at this time, submit a timetable for curing the material breach for the OIG's approval.

If at the conclusion of the thirty-five (35) day period (or other specific period as subsequently agreed by OIG and SJMC), SJMC fails to act in accordance with provisions (1), (2) or (3) above, OIG may exclude SJMC from participation in the Medicare, Medicaid and all other Federal health care programs. OIG will notify SJMC in writing of its determination to exclude SJMC (this letter shall be referred to hereinafter as the "Exclusion Letter").

Notwithstanding any provisions in Chapter 42 of the Code of Federal Regulations, the exclusion shall take effect thirty (30) days from the date of the Exclusion Letter unless SJMC exercises its contractual right to seek review of the OIG's exclusion determination by requesting a hearing before an administrative law judge as provided in section VIII.D below. In the event SJMC requests such a hearing, the exclusion shall not be effective until the issuance of an administrative law judge's decision supporting the OIG's exclusion determination. The exclusion shall have national effect and will also apply to all other Federal procurement and non-procurement programs.

For purposes of this section, a "material breach" shall mean: (i) a failure to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.D. of this Agreement; (ii) repeated or flagrant violations of the obligations under this Agreement, including, but not limited to, the obligations addressed in section VIII.A of this Agreement; or (iii) failure to respond to a Demand Letter concerning the payment of stipulated penalties in accordance with section VIII.B above.

In connection with the OIG's determination to exclude SJMC pursuant to this provision, SJMC shall have the right to dispute the OIG's determination in accordance with the agreed upon provisions set forth in section VIII.D of this Agreement.

#### **D. DISPUTE RESOLUTION**

Upon OIG's delivery to SJMC of its Demand letter or Exclusion Letter, and as an agreed upon contractual remedy for the resolution of disputes arising under the

obligations in this Agreement, SJMC shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the stipulated penalties or exclusion sought pursuant to this Agreement. Specifically, the OIG's determination to demand payment of stipulated penalties or to seek exclusion shall be subject to review by an HHS administrative law judge in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. The administrative law judge's decision, in turn, may be appealed to HHS's Departmental Appeals Board ("DAB") in a manner consistent with the provisions in 42 C.F.R. § 1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving stipulated penalties shall be made within ten (10) days of the date of the Demand Letter and the request for a hearing involving exclusion shall be made within thirty (30) days of the date of the Exclusion Letter.

Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for stipulated penalties under this section shall be: (i) whether, on the date of the Demand Letter, SJMC was in full and timely compliance with the obligations in this Agreement for which OIG demands payment; (ii) the period of noncompliance; and (iii) whether SJMC has begun to take action to cure the material breach and that SJMC will pursue such an action with due diligence. For purposes of paying stipulated penalties under this Agreement, and if SJMC chooses to seek review in lieu of curing the breach and paying the stipulated penalties, as set forth above, the administrative law judge's decision shall give rise to SJMC's obligation to pay. Thus, payment will be due twenty-five (25) days from the day the administrative law judge's decision is issued. SJMC's election of its contractual right to appeal to the DAB shall not excuse its obligation to make payment upon the issuance of the administrative law judge's decision.

Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this Agreement shall be: (i) whether SJMC was in material breach of one or more of its obligations under this Agreement; and (ii) whether the alleged material breach was continuing on the date of the Exclusion Letter. For purposes of the exclusion herein agreed to, in the event of a material breach of this Agreement, an administrative law judge's decision finding in favor of the OIG shall be deemed to make the exclusion effective, at which time the OIG may proceed with its exclusion of SJMC. The administrative law judge's decision

may be appealed to the DAB in a manner consistent with the provisions in 42 C.F.R. § 1005.21.

Neither the review by an administrative law judge nor the potential subsequent review of the administrative law judge's decision by the DAB, as provided for above, shall be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this Agreement agree that the DAB's decision shall be considered final for all purposes under this Agreement and shall not be appealed either administratively or judicially or otherwise be subject to review by any court or other adjudicative forum.

#### **IX. EFFECTIVE AND BINDING AGREEMENT**

Consistent with the provisions in the Settlement Agreement pursuant to which this Agreement is entered, and into which this Agreement is incorporated, SJMC and the OIG agree as follows:

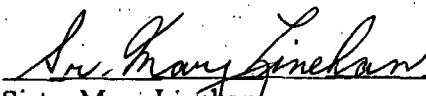
- (1) this Agreement shall be binding on the successors, assigns and transferees of SJMC;
- (2) the effective date of this Agreement shall be the date the final signature is obtained on the Settlement Agreement;
- (3) any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement; and
- (4) the undersigned SJMC signatory represents and warrants that they are authorized to execute this Agreement. The undersigned United States signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

IN WITNESS WHEREOF, the parties hereto affix their signatures:

#### **ST. JOSEPH'S MEDICAL CENTER**

Date

6-4-99

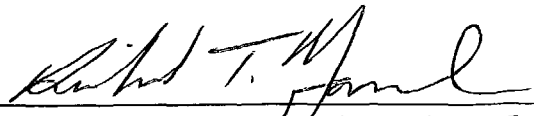
  
Sister Mary Linchan  
President  
St. Joseph's Medical Center.

Corporate Integrity Agreement Between the  
United States and St. Joseph's Medical Center  
June 3, 1999

St. Joseph's Medical Center.

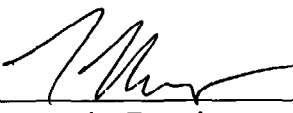
**ST. JOSEPH'S MEDICAL CENTER, CONT.**

Date June 4, 1999

  
Nixon, Hargrave, Devans & Doyle, LLP  
Richard T. Yarmel, Esquire  
Counsel for St. Joseph's Medical Center  
(716) 263-1043

**OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Date 6/3/99

  
Lewis Morris, Esquire  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
U. S. Department of Health and Human Services